

INFECTIOUS WASTE TREATMENT PERMIT

Permit Number IWMP

Issue Date:
Expiration Date:

Effective Date:
Date Last Modified:

This Permit is hereby issued to: TreatMed, Inc.

Owner/Operator: TreatMed, inc.
Address: 130 Franke Drive
Spartanburg, SC 29307

Facility Contact: Mr. Dave Squalli
Phone: (917) 855-6621

This permit is issued for the receipt, handling, temporary storage and treatment of infectious waste. The permitted storage area has a capacity not to exceed a maximum of sixty-four thousand (64,000) pounds at any given time. The permitted treatment facility uses steam sterilization (autoclave) with a treatment capacity of one thousand three hundred twenty five (1325) pounds per cycle per unit, up to a maximum of twenty three million (23,000,000) pounds per year as set in accordance with Section 44-93-210. The facility is located on 130 Franke Drive, Spartanburg, South Carolina in Spartanburg County.

This permit is issued pursuant to 44-93-10 et. seq., South Carolina Infectious Waste Management Regulations, R.61-105 of the 1976 South Carolina Code of Law, as amended. The authority granted hereunder is subject to the requirements of the aforementioned laws and regulations and the following conditions:

Richard Haynes, P.E., Director
Division of Waste Management
Bureau of Land and Waste Management

This Permit is the property of the Bureau of Land and Waste Management and must be surrendered on demand. The Department may, upon written request from the Permittee and approved by the Department, transfer this permit to a new owner or operator. This signature page must be posted at all times in a conspicuous place on the premises.

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TreatMed, Inc.
IWMP
Spartanburg County

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TABLE OF PERMIT MODIFICATIONS

**TreatMed, Inc.
IWMP
Spartanburg, SC**

Effective Date	Class, Location [e.g. Permit Condition(s) and/or Part B Section], and Description of Change
<Date>	<Module Description>

MODULE I - STANDARD CONDITIONS

Module I.

I.A. MODULE DESCRIPTION

The permit is issued pursuant to the South Carolina Infectious Waste Management Act. The Permittee is allowed to handle, temporarily store, and steam sterilize (autoclave) infectious waste in accordance with the conditions of this permit. Any storage, treatment, and/or disposal of infectious waste not specifically authorized by this permit is prohibited. Issuance of this permit does not convey property rights of any sort or any exclusive privilege; nor does it authorize any injury to persons or property, any invasion of other private rights, or any infringement of state or local law or regulation. Compliance with the terms of this permit does not constitute a defense to any order issued or any action brought under the South Carolina Infectious Waste Management Act or R.61-105.

I.B. PERMIT ACTIONS

I.B.1. Permit Modification, Revocation and Reissuance, and Termination

This permit may be modified, revoked and reissued, or terminated for cause as specified in R.61-105. The filing of a request for a permit modification, revocation and reissuance, termination or the notification of planned changes or anticipated noncompliance on the part of the Permittee does not stay the applicability or enforceability of any permit condition.

I.B.2. Permit Renewal

This Permit may be renewed as specified in R.61-105 and Permit Condition I.E.2. Application for permit renewal shall consider improvements in the state of control and measurement technology, as well as changes in applicable regulations.

I.B.3. Permit Expiration

This Permit shall be effective for 10 years. This Permit and all Conditions herein will remain in effect beyond the permit's expiration date, if the Permittee has submitted a timely, complete application, which meets the Department's requirements.

I.C. SEVERABILITY

The provisions of this Permit are severable, and if any provision of this Permit, or the application of any provision of this Permit to any circumstance is held invalid, the application of such provision to other circumstances and the remainder of this Permit shall not be affected thereby.

I.D. DEFINITIONS

For purposes of this Permit, terms used herein shall have the same meaning as those in R.61-105, Section D unless this Permit specifically provides otherwise; where terms are not defined in the regulations or the permit, the meaning associated with such terms shall be defined by a standard dictionary reference or the generally accepted scientific or industrial meaning of the term.

I.D.1. Contamination

For the purposes of this permit refers to the presence of any infectious waste in the immediate vicinity of the facility which is manifested to that facility and is no longer held in the primary containment system.

I.D.2. Department

For purposes of this permit means the Department of Health and Environmental Control, including personnel thereof authorized by the Board to act on behalf of the Department or Board.

I.D.3. Hazardous waste

For the purposes of this permit are those substances defined as Resource Conservation and Recovery Act (RCRA) hazardous waste as defined in R.61-79.261, Subpart A, Section 261.3 of the S. C. Hazardous Waste Management Regulations.

I.D.4. Infectious Waste Management Unit

For the purposes of this permit includes any unit which has been used for the treatment, handling, temporary storage, or disposal of infectious waste at any time, irrespective of whether the unit is or ever was intended for the management of infectious waste.

I.D.5. Landfill

For the purposes of this Permit includes any disposal facility or part of a facility where solid waste is placed in or on the land and which is not a pile, a land treatment facility, a surface impoundment, an underground injection well, a salt dome formation, a salt bed formation, an underground mine, a cave, or a remedial action management unit.

I.D.6. Radioactive material

For the purposes of this permit includes any and all equipment or materials which are radioactive or have radioactive contamination and which are required pursuant to any governing laws, regulations or licenses to be disposed of or stored as radioactive material.

I.D.7. The Regulation

For the purposes of this permit is the South Carolina Infectious Waste Management Regulation, R.61-105.

I.D.8. Release

For purposes of this Permit includes any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment of any infectious waste or infectious constituents.

I.D.9. Sewage

For the purposes of this permit refers to a Department approved sanitary sewer system or a Department approved sewage treatment facility.

I.D.10. The Application or the Permit Application

For the purposes of this permit is the TreatMed, Inc. initial application dated January 18, 2011 and any Department approved revisions.

I.D.11. The SOP

For the purposes of this permit is the TreatMed, Inc. Operation Plan and Site Safety Manual as indicated in the Permit Application.

I.D.12. A Unit

For the purposes of this permit includes, but is not limited to any: treatment unit, container storage unit, recycling unit, autoclave, chemical disinfection unit, or sanitary sewer.

I.E. DUTIES AND REQUIREMENTS

I.E.1. Duty to Comply

The Permittee shall comply with the approved permit application and all conditions of this Permit, except to the extent and for the duration such noncompliance is authorized by an emergency permit. Any permit noncompliance, other than noncompliance authorized by an emergency permit, constitutes a violation of the South

Carolina Infectious Waste Management Act and is grounds for enforcement action, permit termination, revocation and reissuance, modification, or denial of a permit renewal application. [R.61-105]

I.E.2. Duty to Reapply

If the Permittee intends to continue an activity allowed or required by this Permit after the expiration date of this Permit, the Permittee shall submit a complete application for a new permit at least one hundred eighty (180) days prior to permit expiration.

I.E.3. Permit Expiration

Pursuant to R.61-105. W.(11), this Permit shall be valid for the period stated in the permit. This Permit and all conditions herein will remain in effect beyond the Permit's expiration date, if the Permittee has submitted a timely, complete application (see R.61-105. W.) and, through no fault of the Permittee, the Department has not made a final decision on the application, as set forth in R.61-105.W.

I.E.4. Need to Halt or Reduce Activity Not a Defense

It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

I.E.5. Duty to Mitigate

In the event of noncompliance with this Permit, the Permittee shall take all reasonable steps to minimize releases to the environment, and shall carry out such measures as are reasonable to prevent significant adverse impacts on human health or the environment.

I.E.6. Proper Operation and Maintenance

The Permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the Permittee to achieve compliance with the Conditions of this Permit. Proper operation and maintenance includes effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of a backup or auxiliary facilities or similar systems only when necessary to achieve compliance with the Conditions of this Permit.

I.E.7. Duty to Provide Information

The Permittee shall furnish to the Department, within a reasonable time, any relevant information which the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this Permit, or to determine compliance with this Permit. The Permittee shall also furnish to the Department, upon request, copies of records required to be kept by this Permit.

I.E.8. Inspection and Entry

The Permittee shall allow an authorized representative of the Department access to the facility, upon the presentation of credentials and other documents, as required by law.

I.E.8.(a). Enter at reasonable times upon the Permittee's premises where a regulated activity is located or conducted, or where records must be kept under the Conditions of this Permit;

I.E.8.(b). Have access to and copy, at reasonable times, any records that must be kept under the Conditions of this Permit;

I.E.8.(c). Inspect, at reasonable times, any facilities, equipment (including monitoring and control equipment), practices or operations regulated as required under this Permit; and

I.E.8.(d). Sample or monitor, at reasonable times, for the purposes of assuring permit compliance, any substances or parameters at any location.

I.E.9. Monitoring and Records

I.E.9.(a). Measurements taken for the purpose of monitoring shall be representative of the monitored activity as required by R.61-105 (U)(14).

I.E.9.(b). The Permittee shall retain at the facility copies of all reports, records and manifests require by R.61-105. T, U, W, Y, Z, and AA, and records of all data used to complete the application for this permit, for a period of at least 3 years.

I.E.10. Reporting Planned Changes

The Permittee shall give notice to the Department within thirty (30) days of any planned physical alteration or addition to the permitted facility to include changes that may require a permit modification. The permitted facility is the infectious waste container storage, waste handling, steam sterilizers (autoclaves), and all related activities thereto.

I.E.11. Reporting Anticipated Noncompliance

The Permittee shall give advance notice to the Department of any planned changes in the permitted facility or activity, which may result in noncompliance with permit requirements.

I.E.12. Transfer of Permits

The Department may, upon written request from the Permittee and approved by the Department, transfer his permit to a new owner or operator. The Department may require modification or revocation and reissuance of the Permit pursuant to R.61-105.

I.E.13. Noncompliance Reporting

Written notification of noncompliance shall be submitted in writing within fifteen (15) days of the noncompliance occurrence.

I.E.13.(a). The Permittee shall report to the Department any infectious waste release, detection of radioactive material or identification of hazardous waste, which may endanger health or the environment and is prohibited by Section T (7) of R.61-105. If the noncompliance event occurs during normal business hours, the Permittee shall immediately notify the Infectious and Radioactive Waste Section at 803-896-4000. If the noncompliance event occurs after normal business hours, the Permittee shall notify the Radioactive and Infectious Waste Management Section at 803-896-4000 the next working day. This report shall include the following:

I.E.13.(a)(i) Information concerning the release of any infectious waste which may endanger the public;

I.E.13.(a)(ii) Any information of a release or discharge of infectious waste greater than one (1) gallon or one cubic foot dry waste.

I.E.13.(a)(iii) Information concerning the detection of radioactive material or hazardous waste which may endanger the public or the environment.

I.E.13.(b). The description of the occurrence and its cause shall include:

I.E.13.(b)(i) Name, address, and telephone number of the owner or operator;

I.E.13.(b)(ii) Name, address, and telephone number of the facility;

I.E.13.(b)(iii) Date, time and type of incident;

I.E.13.(b)(iv) Name and quantity of materials involved;

I.E.13.(b)(v) Name of personnel involved and the extent of injuries, if any;

I.E.13.(b)(vi) An assessment of actual or potential hazard to the environment and human health outside the facility, where this is applicable; and

I.E.13.(b)(vii) Estimated quantity and disposition of recovered material that resulted from the incident.

I.E.13.(c). A written submission shall also be provided to the Department within fifteen (15) days of the time the Permittee became aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period(s) of noncompliance (including exact dates and times); whether the noncompliance had been corrected; and if not, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent recurrence of the noncompliance. The written report shall contain the above as well as the information specified under condition I.E.13(a) and (b).

I.E.14. Other Noncompliance

The Permittee shall report all other instances of noncompliance not otherwise required to be reported by Permit Conditions I.E.11 and 13 at the time monitoring reports as stated in I.E. 9. are submitted. The reports shall contain the information listed in Condition I.E.13.

I.E.15. Other Information

Wherever the Permittee becomes aware that he failed to submit any relevant facts in the permit application, or submitted incorrect information in a permit application or in any report to the Department, the Permittee shall promptly submit such facts or information to the Department.

I.E.16. Imminent Hazard Reporting

The Permittee shall report to the Department ¹ any noncompliance, imminent or existing hazard from a release of hazardous waste or hazardous constituents, or from a fire or explosion at the facility, which may endanger human health or the environment. The Permittee shall also report any fire or explosion at or near a permitted unit or other hazardous waste management area. Such information shall be reported orally within one (1) hour from the time the Permittee becomes aware of the circumstances. This report shall include the following:

I.E.16.(a)(i) Information concerning the release of any hazardous waste or hazardous constituents that may endanger public drinking water supplies.

I.E.16.(a)(ii) Information concerning the release or discharge of any hazardous waste, or hazardous constituents, or a fire or explosion at the facility, which could threaten the environment or human health outside the facility, or of any fire or explosion at or near a permitted unit or other hazardous waste management area at the facility.

I.E.16.(b). The description of the occurrence and its cause shall include:

¹ In this instance, the Emergency Response Section, the District, and the Bureau of Land and Waste Management Infectious and Radiological Waste at 803-896-4000, must be contacted. The Emergency Response toll free 24-hour number is 1-888-481-0125 (in the Columbia area, call 803-253-6488). Please note Emergency Response must be contacted immediately.

- I.E.16.(b)(i) Name, address, and telephone number of the owner or operator;
- I.E.16.(b)(ii) Name, address, and telephone number of the facility;
- I.E.16.(b)(iii) Date, time, and type of incident;
- I.E.16.(b)(iv) Name and quantity of materials involved;
- I.E.16.(b)(v) The extent of injuries, if any;
- I.E.16.(b)(vi) An assessment of actual or potential hazard to the environment and human health outside the facility, and
- I.E.16.(b)(vii) Estimated quantity and disposition of recovered material that resulted from the incident.

I.E.16.(c). A written submission shall also be provided to the Department within fifteen (15) days of the time the Permittee become aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period(s) of noncompliance (including exact dates and times); whether the noncompliance had been corrected; and if not, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent recurrence of the noncompliance. The written report shall contain the above as well as the information specified under condition I.E.13(a) and (b).

I.F. REPORTS, NOTIFICATIONS, AND SUBMISSIONS TO THE DEPARTMENT

All reports, notifications, or other information required by this Permit to be submitted to the Department should be sent to the Department by verifiable delivery at the following address:

S.C. Department Of Health & Environmental Control

Attn: Director

Division Of Waste Management

Bureau Of Land And Waste Management

2600 Bull Street

Columbia, SC 29201

Phone: (803) 896-4000

I.G. CONFIDENTIAL INFORMATION

The Permittee may claim confidential certain information required to be submitted by this Permit.

I.H. DOCUMENTS TO BE MAINTAINED AT THE FACILITY

Until closure is completed, certified by an authorized representative of the Permittee, and verified by the Department, the Permittee shall maintain at the facility the following documents and amendments, revisions, and modifications to these documents:

I.H.1. Permit Application and Effective Infectious Waste Permit
The approved permit application and effective infectious waste permit.

I.H.2. Standard Operating Procedures (SOP)
Manual as required by R.61-105.U.(4) and this permit.

I.H.3. Personnel training documents and records,
As required by R.61-105.U.(8) and this permit.

I.H.4. A log of waste shipments
For a minimum of three (3) year as required by R.61-105.U.(12) and this permit;

I.H.5. Record of accidental releases of infectious waste
For a minimum of three (3) years required by R.61-105.U.(7) and this permit.

I.H.6. Radiological quality assurance test and calibrations
For a minimum of three (3) years as required by R.61-105.U.(10)(d) and this permit.

I.H.7. Closure Plan
As required by R.61-105.W.(7)(m) and W.(12) and this permit.

I.H.8. Manifest copies
For a minimum of three (3) years as required R.61-105.AA.(1) and this permit.

I.H.9. Facility operations logs.
As required by R.61-105.U.(14)(f) and this permit.

I.H.10. All other documents
Required by Module I, Permit Condition E.9 and this permit.

MODULE II - GENERAL FACILITY CONDITIONS

Module II.

II.A. DESIGN AND OPERATION OF FACILITY

The Permittee shall construct, maintain and operate the facility in accordance with the approved permit application, dated October 12, 2011 and all Department approved revisions in a manner, to minimize the possibility of any unplanned sudden or non-sudden release of infectious waste to environment, as required by R.61-105.

II.A.1. The TreatMed facility shall use the ECODAS model T2000 infectious waste treatment unit. This unit has been approved by the Department for use as an alternate treatment technology [R.61-105.T(3)].

II.A.2. The TreatMed facility is permitted to operate a maximum of two (2) of the ECODAS T2000 waste treatment units.

II.B. FACILITY CAPACITY

II.B.1. The TreatMed facility shall store waste in containers, not to exceed a maximum of sixty-four thousand (64,000) pounds at any given time.

II.B.2. The TreatMed facility may treat one thousand three hundred twenty five (1325) pounds per cycle per unit, up to a maximum of twenty three million (23,000,000) pounds per year.

II.C. PERSONNEL TRAINING

The Permittee shall conduct personnel training as required by R.61-105.U(8). This training program shall follow the outline in the TreatMed Operation Plan. The Permittee shall maintain and submit training documents and records, as required by R.61-105.U(8) and Module VIII of this permit.

II.D. MANIFEST SYSTEM

Manifests for all shipments received for treatment shall be retained as required by R.61-105.Y.

II.E. FINANCIAL ASSURANCE FOR FACILITY CLOSURE

The Permittee shall demonstrate continuous compliance with R.61-105 by providing documentation of financial assurance, as required by R.61-105. W.(12) & (13). Within thirty (30) days of the effective date of this permit, the Permittee shall submit to the Department documentation of financial assurance in the form of an insurance policy, bond or letter of credit, as required by this condition for Department approval. Changes in financial assurance mechanisms or amounts must be submitted to the Department for approval pursuant to R.61-105.W(12).

Financial assurance must include the most recent Department approved closure cost estimate, as required in R.61-105 W(12). The Permittee must update this amount annually for inflation using the most recent Implicit Price Deflator for Gross National Product published by the U.S. Department of Commerce in its "Survey of Current Business". If the Department or the permittee determines that the current financial assurance coverage is no longer adequate for facility closure and necessary remedial action due to changes in the design, operation, or condition of the facility, the Permittee must increase the financial assurance to the amount necessary to cover these costs within thirty (30) days of the occurrence of such changes. The Permittee must immediately notify the Department upon loss of the financial responsibility coverage as required by R.61-105 W(13). The Permittee shall cease to treat or store infectious waste upon loss of financial responsibility coverage.

II.F. LIABILITY REQUIREMENTS

The Permittee shall demonstrate continuous compliance with R.61-105. W. (12) to have and maintain liability coverage for sudden and accidental occurrences in the amount of at least \$1 million per occurrence exclusive of legal defense costs. Within thirty (30) days of the effective date of the permit, the Permittee shall submit to the

Department documentation of liability coverage as required by this condition for Department approval. The Permittee must immediately notify the Department upon loss of the financial responsibility coverage as required by R.61-105 W. (13). The Permittee shall cease to treat or store infectious waste upon loss of financial responsibility coverage.

MODULE III - WASTE HANDLING PROCEDURE

Module III.

III.A. MODULE DESCRIPTION

This permit module covers the Permittee waste handling procedures at TreatMed, Inc. Waste handling procedures consist of the proper usage of personnel protective equipment, radiological monitoring, and other specific requirements for handling waste.

III.B. PERSONNEL PROTECTIVE HANDLING EQUIPMENT

All personnel handling infectious waste shall wear a company approved uniform, steel toe safety boots with steel in-soles, and appropriate gloves. All personnel shall adhere to the guidelines in the Operation Plan and Site Safety Manual.

III.C. RADIOLOGICAL MONITORING

All infectious waste containers shall be monitored for radioactivity on every load received as required by R.61-105 (U)(10) and the Operation Plan.

III.D. RELEASE PLAN PROCEDURE

III.D.1. Infectious Waste releases shall be contained and disinfected as required by R.61-105 (U)(7).

III.D.2. Appropriate personal protective equipment, as specified in the Operation Plan and Site Safety Manual shall be available and used in the event of a release.

III.D.3. Repackage of leaking waste containers must comply with regulation R.61-105 Section I. and J.

III.D.4. All spills of infectious waste shall comply with Regulation R.61-105 Section U(7).

III.D.5. The Permittee must have in place a written policy requiring continuous policing all areas of the facility for waste.

III.E. UNLOADING AND HANDLING

III.E.1. Procedures for safely unloading and handling infectious waste shall comply with R.61-105 (U)(1 through 13).

III.F. PROCEDURE FOR RESIDUE DISPOSITION

After appropriate treatment, the residue must be disposed of in accordance with R.61-105 T.(4) and in accordance with the South Carolina Solid Waste Management regulations 61-107.5.

MODULE IV - CONTAINER STORAGE AREAS AND CONTAINERS

Module IV.

IV.A. MODULE DESCRIPTION

This permit module is for the infectious waste treatment facility containers storage area at TreatMed, Inc. A complete description of the container storage area can be found in the Site Report and Preliminary Design Plan. Infectious waste will be stored in the waste storage area equipped and operated according to R. 61-105 Section K. The storage area has a capacity not to exceed a maximum of sixty-four thousand (64,000) pounds at any given time. The type of wastes that are stored in the container storage area at the facility shall be maintained as specified in Sections 8, 9 and 10 Operation Plan.

IV.B. PERMITTED AND PROHIBITED WASTE IDENTIFICATION

IV.B.1. The Permittee may

IV.B.1.(a). treat wastes defined as Infectious Waste by the South Carolina Infectious Waste Management Regulations R.61-105 and as allowed by this permit.

IV.B.1.(b). apply in writing to the Department to receive new waste streams which the Department may approve or deny.

IV.B.2. The Permittee is prohibited

IV.B.2.(a). from receiving and temporarily storing any other waste in the storage area including, but not limited to

IV.B.2.(a)(i) radioactive waste as defined by R. 61-63 Title A Radioactive Materials Regulations,

IV.B.2.(a)(ii) hazardous waste as defined by R.61-79.261,

IV.B.2.(b). To treat chemotherapeutic waste, products of conception, large recognizable body parts as defined by R.61-105, and confiscated street drugs.

IV.B.2.(c). Any suspected prohibited waste shall be stored in the special waste handling area in such a manner as to prevent releases (i.e. drum overpaks, curbed containment or storage pallets).

IV.C. CONDITIONS OF CONTAINERS

If a container holding infectious waste is not in good condition (e.g. crushed or cracked) or if it begins to leak, the Permittee shall repackage the waste according to Section I and J of the Infectious Waste Management Regulations R.61-105; or immediately transfer the container to the steam sterilizer (autoclave) for treatment.

IV.D. PACKAGING AND LABELING

All infectious waste stored at the facility shall be packaged in accordance with Section I and labeled in accordance with Section J of the Infectious Waste Management Regulations R.61-105.

IV.E. CLOSURE

At closure of the container storage areas, the Permittee shall comply with the approved closure plan outlining the removal of all infectious waste and the disinfection of infectious management units. Closure IS NOT FINAL until disinfection is completed and approved by the Department.

IV.F. TRAILER/TRANSPORT TEMPORARY STORAGE

Under no circumstances may loaded trailers or loaded transport vehicles be kept at the TreatMed facility for longer than is necessary to complete the unloading process (maximum of eight (8) hours).

IV.G. RECORD KEEPING

A log indicating arrival and departure times, point of origin, weight of waste, time of disinfection, and number of containers in all trucks will be kept by the facility.

MODULE V – MAINTENANCE AND PERFORMANCE

Module V.

V.A. MODULE DESCRIPTION

Valid maintenance and performance activities are directed toward ensuring that equipment continuously supports the requirements of the process. Efficient operation of an autoclave system requires an aggressive preventive maintenance program.

V.B. MAINTENANCE REQUIREMENTS

- V.B.1. The Permittee must adhere to the maintenance program as outlined in the Operation Plan.
- V.B.2. A maintenance inspection checklist shall be completed daily and maintained at the facility for a minimum of 3 years. Copies will be made available to the Department upon request.
- V.B.3. A one-year continuous schedule of major maintenance/repair/replacement forecast for the facility's operating equipment shall be submitted annually to the Department.

V.C. FACILITY OPERATING PERFORMANCE

- V.C.1. All mechanical problems with the autoclaves or associated handling equipment shall be repaired within a single eight-hour shift, or a maximum 24-hours. Attention to such maintenance is dependent on the scope or involvement of the maintenance with 24-hours being a maximum limitation. Any repair requiring greater than 24 hours must be fully described and documented with a scheduled time frame. A copy of this schedule and documentation will be reported to the Department and updated if any deviation is determined.
- V.C.2. Calibration, adjustments, or repair on any monitoring, electronic, or specialized equipment will be performed only by manufacturer's serviceman/technicians; or by manufacturer trained plant designated personnel. Credentials of qualified plant personnel will be provided to the Department upon request. Credentials must include issuer, equipment qualified thereon, and the date of the next re-qualification review/testing. Any personnel that are "certified" are to be listed indicating similar type information as described above.
- V.C.3. All control equipment is to be reviewed annually by a certified contractor/manufacture's technician. The Permittee will coordinate the annual review with the Department so that a representative of the Department may be present during the review.
- V.C.4. Radiation detection equipment is to be tested weekly and calibrated annually to ensure sensitivity. The results of the testing and instrument calibration records shall be available for review by the Department.
- V.C.5. The Permittee is required to perform daily testing as specified in R. 61-105 (U)(14)(a) and (e) using the biological indicator Bacillus stearothermophilus.
- V.C.6. The Permittee is allowed to treat one thousand three hundred twenty five (1325) pounds per cycle per unit, up to a maximum of twenty three million (23,000,000) pounds per year. However, the maximum capacity is only allowed if the Permittee can meet the requirements of this permit.
- V.C.7. The Permittee shall operate the sterilizers, according to the alternate treatment technology request, at a minimum temperature of 280 degrees Fahrenheit and fifty-five (55) pounds of pressure for a minimum of ten (10) minutes to achieve sterilization of the entire load.

MODULE VI - HOUSEKEEPING

Module VI.

VI.A. MODULE DESCRIPTION

All work areas shall be maintained in a clean and sanitary condition. Industrial housekeeping is essential in contamination control, especially when infectious materials are present.

VI.B. HOUSEKEEPING REQUIREMENTS

- VI.B.1. The use of red infectious waste plastic bags with the “biohazard” symbol clearly marked to identify hazards are for biomedical waste purposes only. The use of these red biohazard plastic bags as “trash bags” or for “any other purpose” other than biomedical waste is prohibited.
- VI.B.2. Any biohazard material release, leakage, or similar occurrence will be immediately addressed/cleaned up and properly disinfected in accordance with MODULE X: DISINFECTION.
- VI.B.3. All absorbents and absorbents containing any biohazard materials will be deposited into containers and immediately autoclaved or otherwise managed in accordance with the requirements in R.61-105 (L).
- VI.B.4. No standing water or liquid will be allowed within the confines of the building with the exception of designated locations, i.e. boiler.
- VI.B.5. Adequate lighting within the facilities is required for all work areas, passageways, and other areas where waste is stored or handled. All lamps and lighting fixtures are to be periodically cleaned to maintain proper illumination.
- VI.B.6. All removable items (e.g., equipment, tools, clothing, PPE) are to be decontaminated in accordance with the requirement in Module X prior to a worker leaving a work area where the subject items have been in contact with or have been used in the treatment of infectious, biomedical, or biohazardous waste.
- VI.B.7. All areas where infectious, biomedical, or biohazardous materials are handled shall be properly posted.
- VI.B.8. Any waste, debris, or trash that has fallen in or around the area surrounding the autoclave or other areas where infectious waste is handled shall be immediately cleaned up and disinfected in accordance with MODULE X: DISINFECTION.

MODULE VII – EMERGENCY PREPAREDNESS, SAFETY AND SECURITY

Module VII.

VII.A. MODULE DESCRIPTION

The purpose of Module VII is to ensure the Permittee is prepared to respond to facility emergencies effectively and in a timely manner. Knowing when and what actions to take during emergencies saves lives, and reduces the damage to property. Fire safety is important due to the nature of the thermal treatment process. Security of the facility is important due to the potential for spread of infectious substances by unauthorized personnel.

VII.B. EMERGENCY PREPAREDNESS

The Permittee shall follow Operation Plan Section 15 for establishing emergency preparedness and emergency response activities. The Permittee shall maintain a current contact list of TreatMed Emergency Coordinators, State, and Local emergency responders. This emergency contact list shall be located in an area that is readily available in the event of an emergency.

VII.C. FIRE SAFETY REQUIREMENTS

The facility shall be designed and equipped with a fire protection system that meets local fire codes and is capable of extinguishing a fire in a manner that would limit the spread of contamination. Particular attention should be given to the boiler and autoclave areas, and areas where waste will be handled or stored within the facility. Waste must be stored away from the autoclave area and boiler such that access to these units is not blocked. The operator should also exercise caution around the waste storage, waste charging to the autoclave and the waste removal area.

VII.D. MATERIAL SAFETY DATA SHEET

Material Safety Data Sheets must be posted in a location that is easily accessible, and must contain all chemicals on the facility property.

VII.E. SECURITY

Security shall be provided to prevent unauthorized persons from entering the premises.

MODULE VIII- TRAINING AND EXPOSURE CONTROL PLAN**Module VIII.****VIII.A. MODULE DESCRIPTION**

For any waste treatment process to be effective, workers must be adequately informed and trained. Workers must completely understand their job function and possible consequences for not adequately performing their responsibilities. The Exposure Control Plan is to prevent exposure to blood or other potentially infectious materials (OPIM). The Plan identifies tasks and procedures to reduce exposure to blood and certain body fluids. This requirement of this Module applies to all personnel that are employed at this facility. This includes all full and part-time TreatMed employees, and all contractor employees. The exceptions are those personnel classified as visitors who will not come in direct contact with the waste or contaminated equipment or items. These include (those that will be at the facility for a short duration-normally less than four {4} hours) delivery persons, salesmen, manufacturer technicians, government personnel, common and private carrier trucks drivers, office cleaning individuals, and others that are similarly classified.

VIII.B. SUPERVISORS SHOULD BE

VIII.B.1. Taught the potential health hazards that are present in their work area.

VIII.B.2. Instructed as to when and under what circumstances they should request help in solving problems that involve hazards.

VIII.B.3. Knowledgeable and well informed about all the hazardous processes, operations, and materials for which they are responsible.

VIII.C. WORKERS MUST BE

VIII.C.1. Knowledgeable in the proper operating procedures that allow engineering control to be effective.

VIII.C.2. Taught safe operating procedures through:

VIII.C.2.(a). Booklets

VIII.C.2.(b). Instruction signs

VIII.C.2.(c). Labels

VIII.C.2.(d). Safety meetings

VIII.C.3. Given instructions in normal operating procedures when starting a new job.

VIII.C.4. Given a formal indoctrination program when a new employee is assigned to an area where exposures to hazardous material may occur. This special program is to include:

VIII.C.4.(a). The nature of the hazard.

VIII.C.4.(b). The potential results from exposure.

VIII.C.4.(c). The proper use of protection equipment.

VIII.C.4.(d). Explanation of the medical surveillance program.

VIII.C.4.(e). Emergency situation procedures.

VIII.C.4.(f). Decontamination procedures.

VIII.C.4.(g). Health hazardous control measures.

VIII.D. REPORTING REQUIREMENTS

- VIII.D.1. An employee roster will be maintained showing name, social security number, date-of-hire, date of transfer, instructor name, subject covered, and employee signature acknowledgement with current date.
- VIII.D.2. This section applies to TreatMed personnel and to all contractor personnel performing TreatMed facility operation functions.
- VIII.D.3. All employees (and contractor personnel) with occupational exposure must participate in a training program that will be provided during working hours at no cost to the employee.
- VIII.D.4. All employees (and contractor personnel) are to be adequately trained and informed in hygiene techniques and housekeeping rules. A properly administered program is required combined with an employee acknowledgement checklist. This program can be integrated into the Exposure Control Plan and so noted on the employees training record.
- VIII.D.5. The Department may attend and critique training sessions conducted by the Permittee.

VIII.E. EXPOSURE CONTROL REQUIREMENTS

- VIII.E.1. The Permittee shall initiate and review annually the Exposure Control Plan that will be utilized to meet the requirements of OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030.
- VIII.E.2. All employees who are reasonably anticipated to have occupational exposures to skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties shall participate in training programs that cover the 29 CFR 1910.1030 Standard. Training shall be provided as follows:
 - VIII.E.2.(a). At the time of initial assignment to the task where occupational exposure may take place.
 - VIII.E.2.(b). Annual refresher training for all employees shall be provided within twelve (12) months from their previous training date.
 - VIII.E.2.(c). Additional training will be given to an employee whenever changes occur to the employee's duties or as needed.
- VIII.E.3. Training programs shall cover all elements of the 29 CFR 1910.1030 Standard and contain the elements listed below. Each employee shall have an opportunity for interactive questions and answers with the person conducting the training session. The person conducting the training shall be knowledgeable in the subject matter and certified to conduct 29 CFR 1910.1030 training by OSHA. These elements are as follows:
 - VIII.E.3.(a). A general explanation of the epidemiology and systems of bloodborne diseases.
 - VIII.E.3.(b). An explanation of the modes of transmission of bloodborne pathogens.
 - VIII.E.3.(c). Information on the Hepatitis B vaccine such as data of its efficacy, safety, method of administration, and the benefits of being vaccinated shall be presented. The Hepatitis B vaccine shall be offered free of charge to the employee.
 - VIII.E.3.(d). An explanation of the appropriate methods for recognizing task and other activities that may involve exposure to blood OPIM.
 - VIII.E.3.(e). An explanation of the use and limitation of methods that will prevent or reduce exposure including appropriate engineering controls, work practice controls, and PPE.

- VIII.E.3.(f). Information on the type, proper use, location, removal, handling, decontamination, and disposal of PPE.
- VIII.E.3.(g). An explanation of the basis for selection of PPE.
- VIII.E.3.(h). Information on the appropriate action to take and persons to contact in an emergency involving blood or OPIM.
- VIII.E.3.(i). An explanation of the procedure to follow if an exposure incident occurs including the method of reporting the incident and the medical follow-up that will be made available.
- VIII.E.3.(j). Information on the post-exposure evaluation and follow-up following an exposure incident.
- VIII.E.3.(k). An explanation of required signs and labels required by this Plan.
- VIII.E.3.(l). How the employee can obtain an accessible copy of the Bloodborne Pathogen Standard and an explanation of its contents.
- VIII.E.4. The Permittee shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

VIII.F. MEDICAL RECORD KEEPING

The Permittee shall establish and maintain an accurate record for each employee with occupational exposure. This record shall include:

- VIII.F.1. The name and social security number of the employee.
- VIII.F.2. A copy of the employee's Hepatitis B vaccination status, including the dates of all the Hepatitis B vaccinations.
- VIII.F.3. Any medical records relative to the employee's ability to receive vaccination.
- VIII.F.4. A copy of all results of examination, medical testing, and the follow-up procedures.
- VIII.F.5. The employer's copy of the health care professional's written opinion.
- VIII.F.6. A copy of the information provided to the health care professional.

VIII.G. TRAINING RECORDS

The Permittee is responsible for completing a TreatMed form acknowledging and documenting employee training attendance. Individual employee training records shall include the following information:

- VIII.G.1. The dates of the training session.
- VIII.G.2. The contents or a summary of the training session.
- VIII.G.3. The names and qualification of the persons conducting the training.
- VIII.G.4. The names, social security number, work locations, and job titles of all persons attending the training sessions.
- VIII.G.5. Training records shall be maintained for three (3) years from the date on which the training occurred.

MODULE IX – PERSONAL PROTECTIVE EQUIPMENT (PPE)

Module IX.

IX.A. MODULE DESCRIPTION

The purpose of Personal Protective clothing and Equipment (PPE) is to shield or isolate individuals from the chemical, physical, and biologic hazards that may be encountered. PPE is specialized clothing or equipment worn by an employee for protection against a hazard. Careful selection and use of adequate PPE should protect the respiratory system, skin, eyes, face, hands, feet, head, body, and hearing.

IX.A.1. The Permittee shall comply with the Operation Plan and Site Safety Manual when using PPE.

IX.A.2. Copies of the PPE Program are to be distributed to all TreatMed employees and contractor personnel. A reference copy is to be available at each work site. A copy of the PPE program is to be made available to the Department upon request.

IX.A.3. The PPE program is to be reviewed annually by the TreatMed Safety Officer.

MODULE X – DISINFECTION

Module X.

X.A. MODULE DESCRIPTION

The proper method to disinfect all items associated with infectious, biomedical, and medical waste is important to ensure worker safety.

X.A.1. SC Regulation R.61-105 (L) and (U)(7) pertains to “Disinfection”.

X.A.2. Infectious waste spills shall be handled according to R.61-105 (U)(7). An EPA registered tuberculocidal disinfectant shall be used according to the manufacturers’ label when cleaning up spills.

X.A.3. Disinfecting of carts and containers shall be conducted according to the TreatMed Operation Plan Sections 10 and 11 before reuse.

MODULE XI – FEES ON COMMERCIAL TREATMENT OF INFECTIOUS WASTE

Module XI.

XI.A. MODULE DESCRIPTION

TreatMed, Inc. shall comply with the South Carolina Infectious Waste Management Act Section 44-93-160 for submitting fees based on the amount of infectious waste received for treatment.

XI.A.1. The Fee is calculated on calendar month waste receipts and is based on the pre-treated weight of the waste as required by the South Carolina Infectious Waste Management Act Section 44-93-160.

XI.A.2. The Permittee shall submit a detailed report describing the total weight of infectious waste received for treatment during the preceding month and its point of origin.

XI.A.2.(a). The Permittee shall make a check payable to South Carolina Department of Health and Environmental Control for the fee due for the preceding month. The check should be submitted to:

South Carolina Department of Environmental Control

2600 Bull Street

Columbia, South Carolina 29201

Attention: Bureau of Finance

XI.A.2.(b). Penalties remaining unpaid thirty (30) days after billing will be issued at a late notice with no penalty due; however, it will contain a notice of penalty for non-payment after sixty (60) days. Fees remaining unpaid after sixty (60) days will be assessed a ten percent (10%) penalty. Permittees delinquent will be issued a notice of the ten percent (10%) penalty due the Department as well as notice of further penalties should fee remain unpaid. Fees remaining unpaid at the end of of ninety (90) days will be assessed a twenty-five percent (25%) penalty in addition to the ten percent (10%) penalty. The sum of both penalties may not exceed five thousand dollars. Persons delinquent at the end of ninety (90) days under this paragraph will be notified by the Department by certified mail at their last know address.

XI.A.2.(c). Returned checks will be subject to a returned check fee as outlined in the DHEC Administrative Policy and Procedures Manual. This fee will be in addition to those outlined in paragraph XI.A.2 (b).

XI.A.2.(d). Failure to pay fees may, after a hearing in accordance with the provisions of Section XI.A.4, result in the revocation of an existing permit, license, registration, or certification.

XI.A.3. Any person required to pay a fee established pursuant to this regulation, who disagrees with the calculation or applicability of the fee, may submit to the Department a petition for a hearing together with the total amount of fee assessed by the Department. The petition must comply with the requirements of Regulation 61-72 and must identify the fee, which is challenged and set forth the grounds on which relief is sought. The Department must receive such petition, and the full amount of the fee due, no later than thirty (30) days after the due date. The hearing shall be in accordance with Regulation 61-72, Procedures for Contested Cases, and the State Administrative Procedures Act. If, through the appeals process, it is determined that the fee

was improperly assessed, the Department shall return the amount determined to be improperly assessed with interest not to exceed the statutory rate.

- XI.A.4. A report detailing the total weight of infectious waste received for treatment during the preceding month and its point of origin. This report should be submitted in accordance with Section I.F. of this permit along with a copy of the check required in XI.A.2.(a).
- XI.A.5. Any amendments to the Infectious Waste Management Act, which changes the fees, will supersede the requirements in this module.